

## BOARD OF PHARMACY

### Final Statement of Reasons

Subject Matter of Proposed Regulations: Pharmacist-In-Charge

Section Affected: Title 16, Section 1709.1

Hearing Date: April 21, 2004

#### Updated Information

None.

#### Summary of Comments Received During the 45-Day Comment Period (February 20, 2004 to April 5, 2004).

In a letter dated March 18, 2004, Mr. Kenneth E. Sain questioned the justification for allowing a single pharmacist to be designated pharmacist-in-charge at two locations.

The board disagreed with this comment. Existing law requires a pharmacist-in-charge to be responsible for the lawful operation of the pharmacy. This role does not require the continuous presence of the pharmacist-in-charge in the pharmacy. The board believes that a single individual is capable of performing the management functions required of a pharmacist-in-charge in two pharmacies in reasonable proximity to one another. Permitting a single individual to serve in this role in two pharmacies will allow that pharmacist to specialize in these management functions.

Mr. Sain further commented that permitting a single pharmacist to be pharmacist-in-charge at two locations is inconsistent with existing regulations that prohibit a single pharmacist from being pharmacist-in-charge at both a pharmacy and a wholesaler.

The board disagrees with this comment. The prohibition on concurrently serving as pharmacist-in-charge in both a wholesaler and a pharmacy has justifications other than appropriate scope of responsibility for that pharmacist. Such a prohibition serves to ensure that each end of a wholesale drug transaction is overseen by separate individuals. Vesting ultimate authority over both ends of a wholesale transaction in the same individual presents potential conflicts of interest and opportunities for inappropriate transactions between the wholesaler and the pharmacy.

Mr. Sain further commented that allowing a single pharmacist to serve as pharmacist-in-charge at two pharmacies would only serve the financial interests of the parties involved and would not protect the public as effectively as the existing regulation.

The board disagreed with this comment.

### Summary of Comments Received During the Regulation Hearing.

Mr. Bruce Young, representing the California Retailers Association, indicated support for the regulation. Mr. Young emphasized the importance of allowing each individual pharmacist to decide whether to become the pharmacist-in-charge at a second pharmacy based their professional judgment. The particular situation at each pharmacy can vary dramatically based on staffing and the practice setting.

The board agrees with this comment.

Mr. Richard Mazzoni, representing Alberston's/SavOn, indicated support for the regulation. Allowing pharmacists with the aptitude and desire to become pharmacist-in-charge at an additional pharmacy will free those pharmacists acting as pharmacist-in-charge who prefer to shed that responsibility.

The board agrees with this comment.

Mr. John Cronin, representing the California Pharmacists Association, indicated support for the regulation. Mr. Cronin emphasized the importance of subdivision (b) of the regulation that requires pharmacy owners to vest the pharmacist-in-charge with the authority needed to assure compliance with the laws governing pharmacy. Mr. Cronin further emphasized the need for the board and other leaders in the pharmacy community to communicate the nature of this responsibility and the rights of a pharmacist to make these judgments.

The board agrees with this comment.

In written form and oral testimony submitted during the regulation hearing Mr. Alan Gordon, representing the California Employee Pharmacist Association, questions why the regulation is being considered by the board when the board indicated that the proposed rule would have no impact on the creation of jobs or businesses.

The board responded that the regulation addresses the management of pharmacies by allowing a single pharmacist to manage two pharmacies simultaneously. The board believes that the creation of new pharmacies or new pharmacy jobs is primarily a function of the demand for prescription drugs and the availability of pharmacies in the service area, not the ability of a single pharmacist to be pharmacist-in-charge at multiple locations. With approximately 6000 pharmacies currently licensed in California and approximately 22,000 licensed pharmacists living in California, the availability of a pharmacist to become pharmacist-in-charge does not appear to be a limiting factor.

In these comments, Mr. Gordon further questions the assertion that California has a shortage of pharmacists and instead posits an overabundance of pharmacies.

The board responded that its statistical analysis of pharmacist workforce in California indicates that California has approximately 67 pharmacists per 100,000 people which is significantly below the national average pharmacist workforce level of approximately 72 pharmacists per 100,000 people.

The board further responded that recent licensing statistics indicate that the population of pharmacists in California is growing faster the growth in the number of pharmacies. Since January 2001 the population of pharmacists has grown approximately 16% while the number of pharmacies has grown approximately 6%. Population growth in the same period was approximately 5%.

In these comments Mr. Gordon further asserts that the proposed regulation would result in an increase in the number of pharmacies in urban areas.

The board responded that the regulation does limit the distance between pharmacies that can have the same individual serving as pharmacist-in-charge, but the 50 mile radius requirement could encompass urban, suburban and semi-rural areas.

In these comments Mr. Gordon further questions whether the board has sufficient resources to respond to complaints from pharmacists who are disciplined after choosing not to serve as pharmacist-in-charge at a second location.

The board responded that the board would devote the resources necessary to investigate such complaints. However, a similar provision relating to pharmacists supervising pharmacy technicians has not generated any complaints to the board.

In these comments Mr. Gordon further indicates that a pharmacist owner may be motivated to place a young and/or unqualified pharmacist as pharmacist-in-charge in order to achieve business goals and that a young pharmacist may be induced to become pharmacist-in-charge at a second pharmacy to earn extra money despite not having the experience needed to perform well.

The board responded that the regulation requires each individual pharmacist to exercise his/her professional judgment in taking such an assignment and that pharmacist is subject to professional discipline should violations occur. The same professional judgment is relied upon when a pharmacist chooses to become pharmacist-in-charge of a single pharmacy. The board believes that there is no evidence that the choice to become pharmacist-in-charge at a second location is inherently more risky than the choice to become pharmacist-in-charge at a single location.

Mr. Steve Gray, representing Kaiser Permanente, indicated support for the regulation. Mr. Gray stated that the regulation will allow greater specialization for those pharmacists with the skills needed to be an effective pharmacist-in-charge. Mr. Gray further stated that this specialization will allow organizations to invest more training in these individuals.

The board agrees with this comment.

Ms. Orriette Quandt, representing Longs Drugs, indicated support for the regulation. Ms. Quandt stated that the regulation will allow high quality pharmacists-in-charge a greater opportunity to mentor other pharmacists by serving at two pharmacies. Ms. Quandt further stated that the regulation will ease the process of obtaining permission for new pharmacies to bill government sponsored health programs because these programs require a pharmacist-in-charge be designated prior to the opening of the pharmacy.

The board agreed with this comment.

Mr. Steve Kyle, a pharmacist, stated that the regulation is unnecessary because a pharmacist can already serve as manager at multiple pharmacies. Mr. Kyle further stated that a pharmacist should only be pharmacist-in-charge at a single pharmacy. Mr. Kyle further stated that such a manager could assist each pharmacist-in-charge.

The board disagrees with this comment. The pharmacist-in-charge is required to be responsible for pharmacy compliance with the law. The regulation was amended to specifically require that the pharmacy owner vest the pharmacist-in-charge with the authority needed to fulfill this responsibility. The board believes that the structure suggested in this comment is inappropriate because it shifts both the authority and responsibility of the pharmacist-in-charge to another individual.

Mr. Kyle further stated that the provision of the regulation prohibiting discipline against a pharmacist for refusing to act as pharmacist-in-charge at a second location was inadequate. Mr. Kyle stated that a pharmacist could be subject to other punishments short of “discipline.”

The board disagreed with this comment.

Local Mandate:

None.

Business Impact:

The board has determined that the proposed regulatory action would have no significant adverse impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

Consideration of Alternatives:

The board has determined that no alternative presented would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.

## BOARD OF PHARMACY

### Final Statement of Reasons Addendum

Mr. Sain further commented that allowing a single pharmacist to serve as pharmacist-in-charge at two pharmacies would only serve the financial interests of the parties involved and would not protect the public as effectively as the existing regulation.

The board disagreed with this comment. The board has found that the current restriction to being a pharmacist-in-charge at a single pharmacy has forced many less experienced pharmacists to take on this responsibility. The board believes that forcing a less experienced pharmacist to become pharmacist-in-charge provides less public protection than sharing the expertise of a single experienced pharmacist at a second pharmacy.

Mr. Kyle further stated that the provision of the regulation prohibiting discipline against a pharmacist for refusing to act as pharmacist-in-charge at a second location was inadequate. Mr. Kyle stated that a pharmacist could be subject to other punishments short of “discipline.”

The board disagreed with this comment. The language of the regulation prohibits an employer from “discriminating” against a pharmacist for declining to serve as pharmacist-in-charge. This language clearly includes other actions short of “discipline” by the employer.

The regulation imposes a 50 mile requirement for serving as pharmacist-in-charge at a second pharmacy. The board determined that 50 miles would be the maximum distance that would allow the pharmacist-in-charge to be present at each pharmacy for a substantial period of time in a single day if that was necessary. In making this determination the board considered varying road conditions in rural areas and the congestion commonly encountered in urban areas. The board drew on its experience with inspectors traveling between pharmacies while conducting inspections.

The regulation language included in subdivision (f) referencing “circumstances of concern” was included to parallel language in a similar provision relating to the supervision of pharmacy technicians. That provision can be found in Business and Professions Code Section 4115 (g) (3).